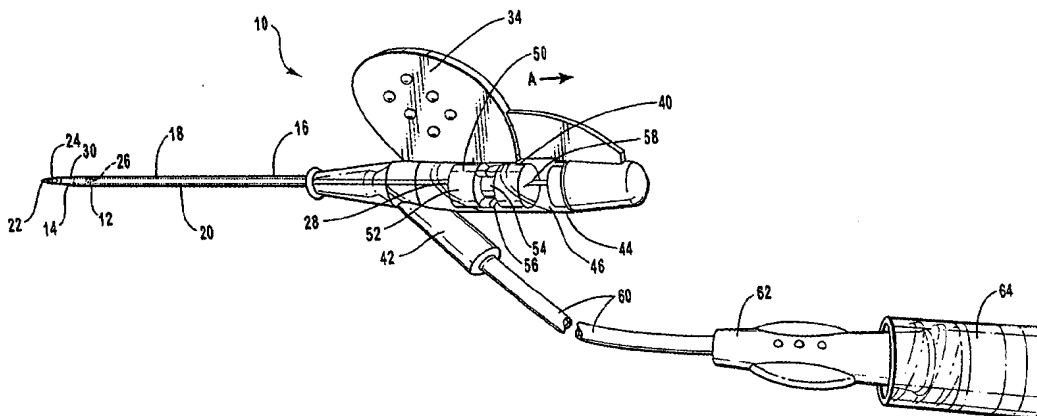




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61M 39/04	A1	(11) International Publication Number: WO 00/12171 (43) International Publication Date: 9 March 2000 (09.03.00)
<p>(21) International Application Number: PCT/US99/19925</p> <p>(22) International Filing Date: 31 August 1999 (31.08.99)</p> <p>(30) Priority Data: 09/145,449 2 September 1998 (02.09.98) US</p> <p>(71) Applicant (for all designated States except US): BECTON, DICKINSON AND COMPANY [US/US]; 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): HOWELL, Glade, H. [US/US]; 1202 East 11000 South, Sandy, UT 84094 (US).</p> <p>(74) Agent: SERVILLA, Scott, S.; Becton Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: BLOOD SEAL HAVING A SPRING-BIASED SEPTUM



(57) Abstract

A blood seal having a spring-biased septum is provided for preventing the leakage of blood during the placement and use of vascular catheters and similar devices. The structure of the blood seal includes a housing with an internal channel. A spring-biased septum is placed securely within the channel such that it substantially blocks blood flow through the channel. The spring-biased septum includes an elastic plug having a pre-slit or pre-molded hole and a biasing element disposed about the elastic plug. A needle or other object may be withdrawn through the slit or hole, after which the biasing element forces the hole closed, preventing blood leakage.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

5

BLOOD SEAL HAVING A SPRING-BIASED SEPTUMBACKGROUND1. The Field of the Invention

The present invention is related to a blood seal having a spring-biased septum
10 for use in connection with various medical devices. More specifically, the present invention relates to a blood seal having a spring-biased septum which is particularly adaptable for use in sealing a vascular access device immediately following placement of a catheter into a blood vessel of a patient.

15

2. Technical Background

During medical treatment, patients often require medication, blood, or fluids. The most efficient way of administering these substances is by depositing them directly into a patient's blood stream where the circulatory system quickly directs the substance to the target tissue or organ. Thus, vascular catheters for infusion of fluids,
20 blood, and medications into patients are among the most commonly used medical devices. The insertion of a vascular catheter allows repeated or continuous access to the circulatory system of a patient. Vascular catheters are generally inserted into the extremities of a patient and fluids, blood, and medications are introduced to the patient through such catheters.

25

Catheters of this type are generally inserted into a vein or artery by means of an introducer needle. In one common configuration, the catheter is initially placed

5 over the needle. The needle, with the catheter located over the needle, is inserted into the patient until the desired vein or artery is located. Once the needle and catheter are properly located in the vein or artery, the needle is withdrawn from the catheter and discarded. The catheter remains in the vein or artery to provide access to the circulatory system of the patient without repeated needle punctures.

10 When the catheter insertion and placement steps have been concluded, one end of a tube (or "tubing set") is generally attached to the proximal end of the catheter. The opposite end of the tube is attached to a source of fluid and medication. The source of fluid is typically a bottle or bag containing the fluid required for treatment of the patient. Once attachment of the catheter to the fluid source is completed, fluids are
15 allowed to flow through the tubing, into the catheter, and ultimately into the patient. In most situations, fluids flow through the tubing set and into the patient by means of gravity feed or using a standard infusion pump.

It will be appreciated that it is important to minimize the leakage of blood to the outside environment during each of the steps described above. Blood leakage can
20 expose medical personnel and others to blood-borne diseases such as AIDS and hepatitis. Blood leakage can contaminate equipment and supplies in the treatment area. Blood leakage may also cause unnecessary alarm on the part of the patient and other observers. Thus, it is important to prevent or minimize blood leakage in order to maintain safety, aesthetics, and to retain equipment and supplies in good working
25 order.

5 The placement and use of catheters of the type described above involve the potential for blood leakage. For example, the removal of the introducer needle once the catheter is in place generally results in a short period of time during which blood may flow out of the catheter to the surrounding environment.

 Attempts have been made to deal with the problem of blood leakage during the
10 placement of catheters. Many of these solutions employ latex or polyisoprene barriers that restrict blood flow. Such a barrier is situated so that after venipuncture and introduction of the catheter into the blood vessel of a patient, the introducer needle is withdrawn through the barrier or plug. Unfortunately, most polymers, including those
15 needle, wire, or cannula remains in the plug for a prolonged period before use. As a result, when the needle is withdrawn through the barrier, the hole left by the needle may fail to reseal, allowing blood to leak from the device.

 Other attempts to deal with the problem of blood leakage typically involve devices that are expensive and complex to operate. For example, one such device
20 employs a relatively complex valve mechanism connected to the proximal end of the catheter which opens when a needle is inserted and then closes when the needle is removed. The valve then opens again when the tubing set is attached to the catheter. This device requires a mechanism for repeated opening and closing of the valve, as well as other collateral structures which facilitate operation of the device. These
25 relatively complex structures complicate the device and add to its cost. In addition, the valve device is designed to remain in place after the tubing set is attached. This

5 increases the potential for irritation and discomfort to the patient. Such devices are also too expensive for wide use in developing countries, where the problem of HIV infection is growing and the need for cost-effective solutions is great.

Accordingly, it would be an advancement in the art to provide a device which would control the flow of blood during the steps surrounding placement and use of a
10 catheter. It would also be an advancement in the art to provide such a device which is inexpensive and simple to operate. It would also be an advancement in the art to provide such a device which could be used without requiring significant modification of conventional catheters, needles, tubing sets and the like. Finally, it would be a significant advancement in the art to provide such a device which provided the
15 medical professional with more control in performing the tasks surrounding placement and use of a catheter.

Such apparatus are disclosed and claimed herein.

BRIEF SUMMARY AND OBJECTS OF THE INVENTION

20 The present invention is a blood seal having a spring-biased septum for preventing the leakage of blood during the placement and use of vascular catheters and similar devices. In one presently preferred embodiment, the blood seal has a housing, at least part of which is substantially cylindrical in configuration. An internal channel through the housing is provided. A spring-biased septum is disposed within and
25 substantially blocks the internal channel. In certain preferred embodiments, the spring-biased septum includes a formed elastic plug with a pre-slit or pre-molded hole.

- 5 In certain preferred embodiments, the elastic plug may be formed of a biocompatible elastomer such as latex or polyisoprene.

In certain preferred embodiments, the elastic plug includes an annular groove in which a biasing element sits. The biasing element is disposed about the elastic plug and keeps the slit or hole closed with a predictable force. In certain preferred
10 embodiments of the present invention, the biasing element is a C-shaped spring constructed of a metal or metal alloy. In certain especially preferred embodiments, the biasing element is a C-shaped spring constructed of spring steel.

It will be appreciated that the biasing element prevents blood flow through the hole or slit, while the elastic plug prevents blood from flowing around the spring-
15 biased septum. In certain embodiments, the housing may be constructed of a soft elastomer. In such embodiments, the spring-biased septum may optionally include a rigid plug retainer that surrounds and radially compresses at least part of the length of the elastic plug, thereby preventing leakage between the plug and the housing. In other embodiments, the housing is constructed of more rigid material, eliminating the
20 need for a rigid plug retainer.

In certain preferred embodiments, the blood seal housing is attached to the catheter during the catheter placement steps. In such embodiments, the housing forms a portion of a connector to which syringes and tubing sets may be attached. In other preferred embodiments, the blood seal housing is distinct from but attached to a
25 connector.

5 The blood seal of the present invention provides a self-closing seal through which an object such as a needle, wire, or cannula may be moved. In certain preferred embodiments, the blood seal allows removal of an introducer needle from a vascular access device. In such embodiments, a portion of the introducer needle is disposed within the slit or hole in the elastic plug. After venipuncture and the introduction of
10 the catheter into the patient's blood vessel, the user withdraws the needle through the blood seal by pulling on a finger grip. After the needle is withdrawn, the biasing element squeezes the elastic plug, closing the hole or slit.

 In other preferred embodiments, the introducer needle is attached to a wire, a portion of which is disposed within the slit or hole in the elastic plug. After proper
15 placement of the catheter, the user withdraws the wire and the needle through the blood seal by pulling a finger grip. As described above, the biasing element forces the hole or slit closed after withdrawal of the wire and needle.

 From the foregoing, it will be appreciated that a spring-biased septum may be used anytime a needle, cannula, wire, or other similar object must pass through a seal.
20 The present invention is especially useful in controlling blood leakage during the placement and use of vascular catheters. Thus, the problems related to blood leakage to the ambient environment are substantially reduced. The present invention also provides a device that is simple and inexpensive to operate, and may be used without significant modification of conventional catheters and tubing sets.

5 These and other objects and advantages of the invention will become apparent upon reading the following detailed description and appended claims, and upon reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

10 In order to more fully understand the manner in which the above-recited advantages and objects of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Please take note that the embodiments illustrated in the drawings are merely illustrative.

15 Figure 1 is a perspective view of one embodiment of a vascular access device incorporating the blood seal having a spring-biased septum of the present invention.

 Figure 2 is a perspective view of the spring-biased septum after the needle has been withdrawn.

 Figure 3 is a cross-sectional view taken along line 3—3 of Figure 2.

20 Figure 4 is a cross-sectional view of the spring-biased septum prior to removal of the needle.

 Figure 5 is a longitudinal cross-sectional view of the blood seal prior to removal of the needle.

 Figure 6 is a partially cut-away plan view of a second embodiment of a
25 vascular access device incorporating the blood seal having a spring-biased septum of the present invention.

5 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

 The present invention can be best understood by reference to the drawings where like parts are designated with like numerals throughout. One embodiment of a vascular access device incorporating the blood seal having a spring-biased septum of the present invention is generally designated 10 in Figure 1. As mentioned above, the
10 vascular access device 10 allows for the placement of a catheter in a patient and subsequent removal of the introducer needle while maintaining a blood seal at the proximal end of the catheter. This allows a medical professional to introduce a catheter into a patient's blood vessel and remove the introducer needle without the need to be concerned about blood leakage.

15 As illustrated in Figure 1, the vascular access device 10 includes a catheter 12. The catheter 12 has a distal end 14, a proximal end 16, and an internal lumen 18. A needle 20 having a sharpened end 22 is slidably mounted within the internal lumen 18 of the catheter 12, such that the sharpened end 22 of the needle protrudes a short distance beyond the distal end 14 of the catheter 12. The sharpened end 22 allows a
20 medical professional to puncture the blood vessel of a patient, creating an access site and facilitating the introduction of the distal end 14 of the catheter 12 into the blood vessel. The distal end 14 of the catheter 12 is tapered, allowing dilation of the access site as the distal end 14 of the catheter 12 is introduced into the blood vessel.

 The needle includes a distal opening 24, a notch-like opening 26, and a lumen
25 30. The lumen 30 permits fluid to flow between the distal opening 24 and the notch-like opening 26.

5 The needle is provided with a proximal end 28 attached to a finger grip 34. The needle 20 extends coaxially through the internal lumen 18 of the catheter, passes through a blood seal 40 disposed within a branched connector 42, and is attached to the finger grip 34, such that after the introduction of at least part of the catheter 12 into the blood vessel, the needle 20 may be withdrawn from the access site by pulling the
10 finger grip 34 in the direction indicated by arrow A, minimizing the risk of injury to the blood vessel.

 The branched connector 42 includes a housing 44 and an internal channel 46 through the housing 44. Disposed within and substantially blocking the internal channel 46 is a spring-biased septum 50. The housing 44, internal channel 46, and
15 spring-biased septum 50 form a blood seal.

 Figure 2 shows a perspective view of the spring-biased septum 50, which includes a dumbbell-shaped elastic plug 52. The elastic plug 52 may be constructed of a biocompatible elastomer. In certain preferred embodiments, the elastic plug 52 is constructed of polyisoprene or latex. The elastic plug 52 has an annular groove 54 in
20 which a biasing element 56 is disposed. In the embodiment shown in Figures 1 and 2, the biasing element 56 is a C-shaped spring. The biasing element 56 may be constructed of a resilient material. In certain preferred embodiments, the biasing element 56 is constructed of a metal or a metal alloy. The biasing element 56 may, for example, be constructed of spring steel.

25 The elastic plug 52 also includes a slit 58 through which the needle 20 passes. It will be appreciated that the slit 58 may be replaced by any of a number of equivalent

5 elements, such as a hole or channel through the elastic plug 52. Prior to use, a portion of the needle 20 is disposed within the slit 58. After the needle 20 is withdrawn, the slit 58 closes to prevent blood leakage.

Figure 3 shows a cross sectional view of the spring-biased septum 50 after the needle has been withdrawn. The elastic plug 52, biasing element 56, and slit 58 are
10 illustrated. From this view, it will be appreciated that the biasing element 56 compresses a portion of the elastic plug 52, keeping the slit 58 closed with a predictable force.

Figure 4 shows a cross-sectional view of the spring-biased septum 50 prior to removal of the needle 20. The needle 20, elastic plug 52, biasing element 56, and slit
15 58 are illustrated. This Figure illustrates the manner in which the needle 20 penetrates the spring-biased septum 50 through the slit 58.

Figure 5 shows a longitudinal cross-sectional view of the blood seal 40 prior to withdrawal of the needle 20 through the spring-biased septum 50. The housing 44,
internal channel 46, and spring-biased septum 50, which includes the elastic plug 52,
20 the annular groove 54, and the biasing element 56 are illustrated.

Returning to Figure 1, the vascular access device 10 includes means for attaching conventional tubing sets and syringes. The branched connector 42 is attached to a tube 60, which is attached to a female adaptor 62. The female adaptor 62 permits removable attachment of syringes or other connectors. The embodiment of
25 the vascular access device 10 shown in Figure 1 also includes an injection piece 64 attached to the female adaptor 62. When the distal end 14 of the catheter 12 is in the

5 blood vessel of a patient, medications may be injected via the injection piece 64. It will be appreciated that other attachment means, such as threaded connectors and luer locks, are well known in the art and may be used with the present invention.

In operation, the user grips the vascular access device 10 by the branched connector 42 (shown in Figure 1) and punctures the blood vessel of a patient with the
10 sharpened end 22 of the needle 20, facilitating the introduction of at least part of the distal end 14 of the catheter 12 into the patient's blood vessel. The notch-like opening 26 allows the user to monitor the placement of the needle 20. Blood flashback through the distal opening 24, into the lumen 30 of the needle 20, and out the notch-like opening 26 verifies blood vessel puncture.

15 After proper placement of the needle 20 and the distal end 14 of the catheter 12 into the patient's blood vessel, the needle 20 is withdrawn to prevent inadvertent damage to the blood vessel. The user withdraws the needle 20 by pulling on the finger grip 34, which is attached to the proximal end 28 of the needle 20, in the direction of arrow A. The sharp tip 22 of the needle 20 is withdrawn through the spring-biased
20 septum 50. The biasing element 56 forces the slit 58 to close, preventing blood leakage. The user may then discard needle 20, which is still attached to finger grip 34, in a container designed for disposal of blood-contaminated sharps or as otherwise might be appropriate.

Removal of the needle 20 leaves the distal end 14 of the catheter 12 in the
25 patient's blood vessel. The user may then introduce a source of fluids or inject medications via the female adaptor 62 or injection piece 64. The means of connecting

5 sources of fluids and medications to the types of connector shown are well known in the art. Fluids and medications flow into the tube 60, through the branched connector 42 and catheter 12, and into the blood vessel of the patient.

A second embodiment of a vascular access device incorporating the spring-biased septum of the present invention is generally designated 110 in Figure 6. The
10 vascular access device 110 includes a catheter 112 having a distal end 114 and a proximal end 116. A needle 120 having a sharpened end 122 is slidably mounted within the catheter 112, such that the sharpened end 122 of the needle protrudes a short distance beyond the distal end 114 of the catheter 112. It will be appreciated that the needle 120 may incorporate openings as described above that permit the user to
15 monitor placement of the needle 120. The sharpened end 122 allows a medical professional to puncture the blood vessel of a patient, creating an access site and facilitating the introduction of the distal end 114 of the catheter 112 into the blood vessel. The distal end 114 of the catheter 112 is tapered, allowing dilation of the access site as the distal end 114 of the catheter 112 is introduced into the blood vessel.

20 The needle 120 is provided with a proximal end 128 attached to a wire 132. At the opposite end of the wire 132 from the proximal end 128 of the needle 120 is a finger grip 134, such that after the introduction of at least part of the catheter 112 into the blood vessel, the needle 120 may be withdrawn from the access site by pulling the finger grip 134, minimizing the risk of injury to the blood vessel. The needle is
25 withdrawn through a tube 136 and a branched connector 142, through a blood seal 140, and into a protective sheath 160. The protective sheath 160 may be as described

5 in U.S. Patent No. 5,304,136 and functions to protect the user from an inadvertent needle stick.

The blood seal 140 includes a housing 144 and an internal channel 146. A spring-biased septum 150 is disposed within and substantially blocks the internal channel 146. The spring-biased septum 150 is formed as described above and includes an elastic plug 152 with an annular groove 154. A biasing element 156 is disposed within the annular groove 154. The elastic plug includes a slit 158. Prior to use, a portion of the wire 132 is disposed within the slit 158. After placement of a portion of the catheter 112 into the blood vessel of the patient, the wire 132 and needle 120 are withdrawn through the slit 158. The biasing element 156 compresses a portion of the elastic plug 152, closing the slit 158 and preventing blood leakage.

The vascular access device 110 includes means for attaching conventional tubing sets and syringes. The branched connector 142 includes a female adaptor 162, permitting removable attachment of syringes or other connectors. It will be appreciated that other attachment means, such as threaded connectors and luer locks, are well known in the art and may be used with the present invention.

In operation, the user punctures the blood vessel of a patient with the sharpened end 122 of the needle 120, facilitating the introduction of at least part of the distal end 114 of the catheter 112 into the patient's blood vessel. After proper placement of the needle 120 and the distal end 114 of the catheter 112 the needle 120 is withdrawn to prevent inadvertent damage to the blood vessel. The user withdraws the needle 120 by pulling on the finger grip 134, which is attached to the wire 132,

5 which, in turn, is attached to the proximal end 128 of the needle 120. The needle 120 is withdrawn from the catheter 112, through the tube 136 and branched connector 142, through the blood seal 140, and into the protective sheath 160. The user may then discard the protective sheath 160.

Removal of the needle 120 leaves the distal end 114 of the catheter 112 in the
10 patient's blood vessel. The user may then introduce a source of fluids or inject medications via the female adaptor 162. Fluids and medications flow through the branched connector 142, tube 136, and catheter 112 and into the blood vessel of the patient.

In summary, the present invention provides a device which controls the flow of
15 blood during the steps involved in the insertion of a catheter. The present invention provides a device which is inexpensive and simple to operate. The blood seal of the present invention can also be used without significant modification of conventional catheters, needles, tubing sets and the like.

The invention may be embodied in other specific forms without departing from
20 its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

5 What is claimed and desired to be secured by Letters Patent is:

1. A spring-biased septum for use in a medical device comprising:
 an elastic plug having a slit disposed longitudinally through the
 plug;
10 a biasing element contacting the plug and disposed such that the
 biasing element urges the longitudinal slit into a closed position.
2. A spring-biased septum as defined in claim 1 wherein the biasing
 element is placed in contact with the outer surface of the elastic plug.
- 15 3. A spring-biased septum as defined in claim 1 wherein said elastic plug
 further comprises an annular groove disposed in the outer surface of the plug.
4. A spring-biased septum as defined in claim 3 wherein said biasing
20 element is disposed within said annular groove.
5. A spring-biased septum as defined in claim 1 wherein said slit is
 formed such that a hypodermic needle can be passed through said slit.
- 25 6. A spring-biased septum as defined in claim 1 wherein the biasing
 element comprises a C-shaped spring.

- 5 7. A spring-biased septum comprising:
 an elastic plug comprising an annular groove;
 a slit disposed longitudinally through the elastic plug; and
 a biasing element contacting said plug and disposed within the
 annular groove of the elastic plug such that the biasing element
10 substantially closes the slit to fluid leakage.
8. A spring-biased septum as defined in claim 7, wherein the elastic plug
 is constructed of a biocompatible elastomer.
- 15 9. A spring-biased septum as defined in claim 7, wherein the elastic plug
 is constructed of latex or polyisoprene.
10. A spring-biased septum as defined in claim 7, wherein the biasing
 element comprises a C-shaped spring.
- 20 11. A spring-biased septum as defined in claim 10, wherein the C-shaped
 spring is constructed of a metal or a metal alloy.
12. A spring-biased septum as defined in claim 10, wherein the C-shaped
25 spring is constructed of spring steel.

- 5 13. A blood seal comprising:
- a housing;
- an internal channel disposed through the housing;
- an elastic plug disposed within and substantially blocking the
- internal channel;
- 10 a slit disposed longitudinally through the elastic plug; and
- a biasing element contacting the elastic plug such that the
- biasing element substantially closes the slit to fluid leakage.
14. A blood seal as defined in claim 13, wherein the elastic plug further
- 15 comprises an annular groove disposed in the outer surface of the plug.
15. A blood seal as defined in claim 13, further comprising a needle
- disposed longitudinally within the internal channel such that at least a portion of the
- needle passes through the hole in the elastic plug.
- 20 16. A blood seal as defined in claim 13, further comprising a wire disposed
- longitudinally within the internal channel such that at least a portion of the wire passes
- through the hole in the elastic plug.
- 25 17. A blood seal as defined in claim 16, wherein the wire is attached to a
- needle.

5 18. A blood seal as defined in claim 13, further comprising a cannula disposed longitudinally within the internal channel such that at least a portion of the cannula passes through the hole in the elastic plug.

 19. A blood seal as defined in claim 13, further comprising a rigid plug
10 retainer disposed within the internal channel such that the rigid plug retainer surrounds and radially compresses at least part of a length of the elastic plug.

 20. A method of introducing a catheter into a blood vessel comprising the steps of:

15 gaining access to the blood vessel by means of a needle comprising a proximal end and a distal end comprising a sharp tip, said needle being disposed longitudinally within a catheter having a proximal end connected to a housing and a distal end, such that the sharp tip of the needle projects beyond the distal end of the catheter and
20 at least part of the proximal end of the needle is disposed within a slit in a spring-biased septum that is disposed within and substantially blocks an internal channel through the housing, said spring-biased septum comprising an elastic plug and a biasing element;

 introducing the distal end of the catheter into the blood vessel;
25 and

5 withdrawing the needle from the blood vessel without removing
the distal end of the catheter from the blood vessel by pulling on a
finger grip attached to the proximal end of the needle such that the
needle is withdrawn through the spring-biased septum.

21. A method of introducing a catheter into a blood vessel as defined in
10 claim 20, wherein the elastic plug comprises an annular groove and the biasing
element is disposed within said annular groove.

22. A method of introducing a catheter into a blood vessel comprising the
steps of:

15 gaining access to the blood vessel by means of a needle
comprising a proximal end and a distal end comprising a sharp tip, said
needle being disposed longitudinally within a catheter having a
proximal end in fluid connection with a housing and a distal end, such
that the sharp tip of the needle projects beyond the distal end of the
20 catheter and the proximal end of the needle is attached to a wire, at
least part of said wire being disposed within a slit in a spring-biased
septum that is disposed within and substantially blocks an internal
channel through the housing, said spring-biased septum comprising an
elastic plug and a biasing element;

25 introducing the distal end of the catheter into the blood vessel;
and

5 withdrawing the needle from the blood vessel without removing
the catheter from the blood vessel by pulling on a finger grip attached
to the wire such that the wire and the needle are withdrawn through the
spring-biased septum.

10 23. A method of introducing a catheter into a blood vessel as defined in
claim 22, wherein the elastic plug comprises an annular groove and the biasing
element is disposed within said annular groove.

1 / 4

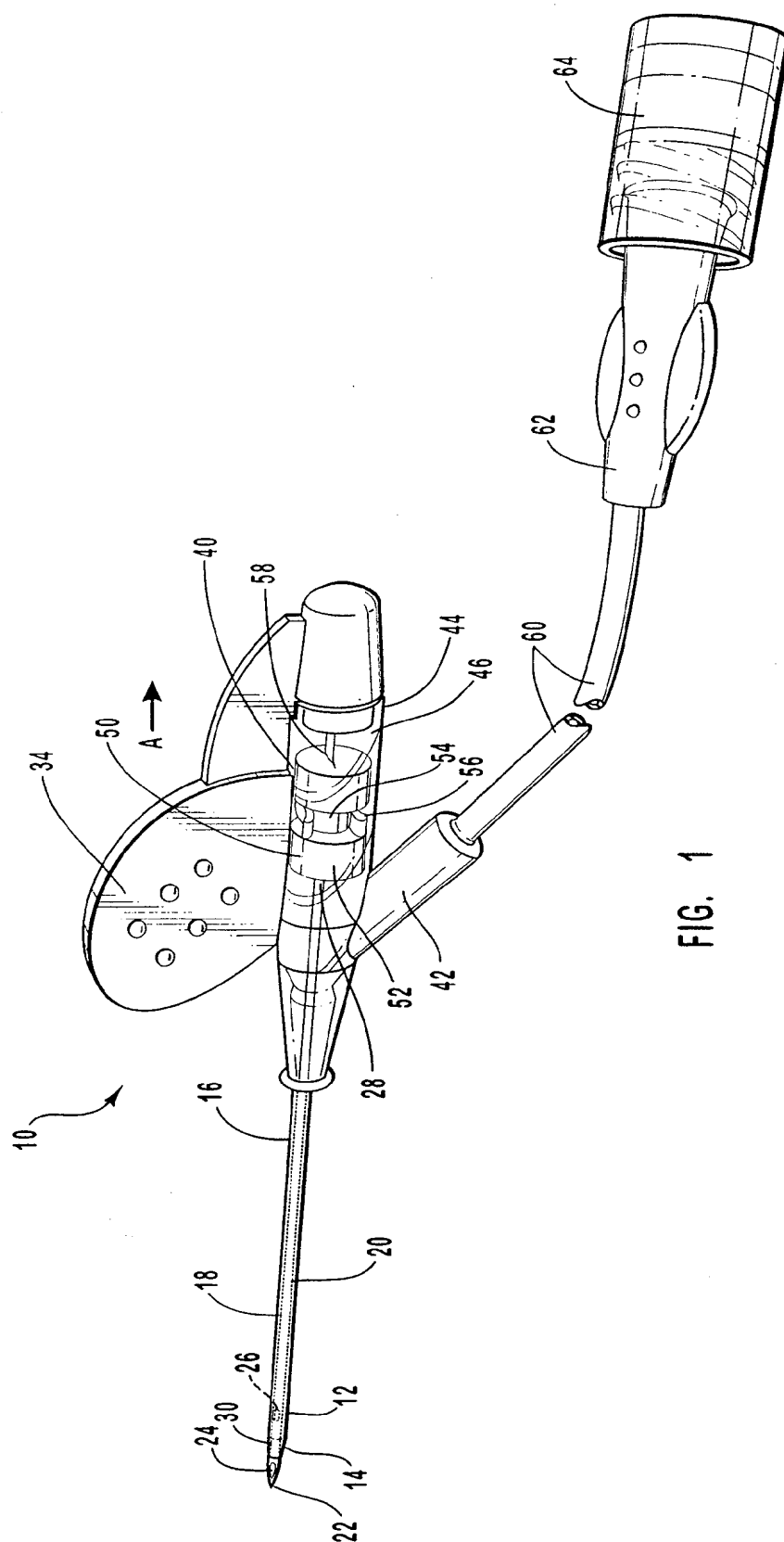


FIG. 1

2 / 4

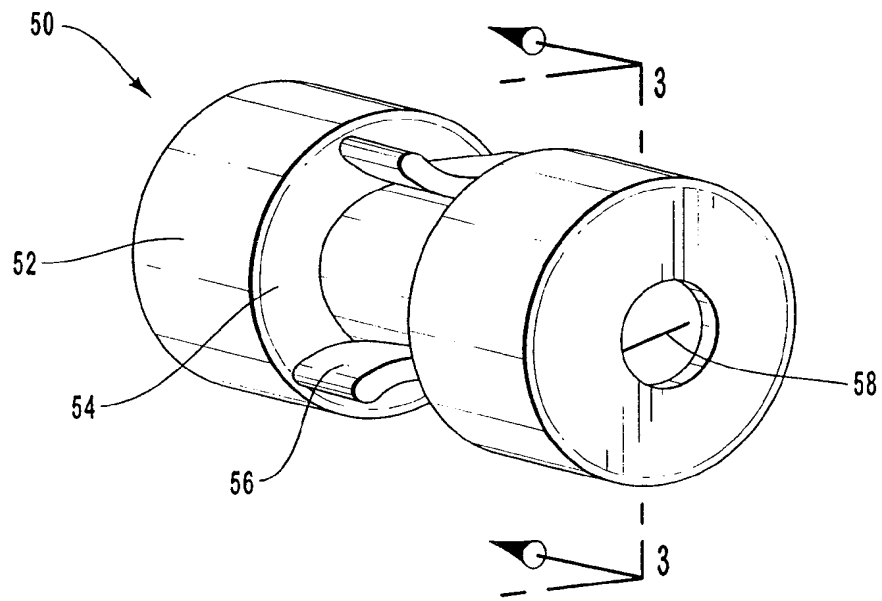


FIG. 2

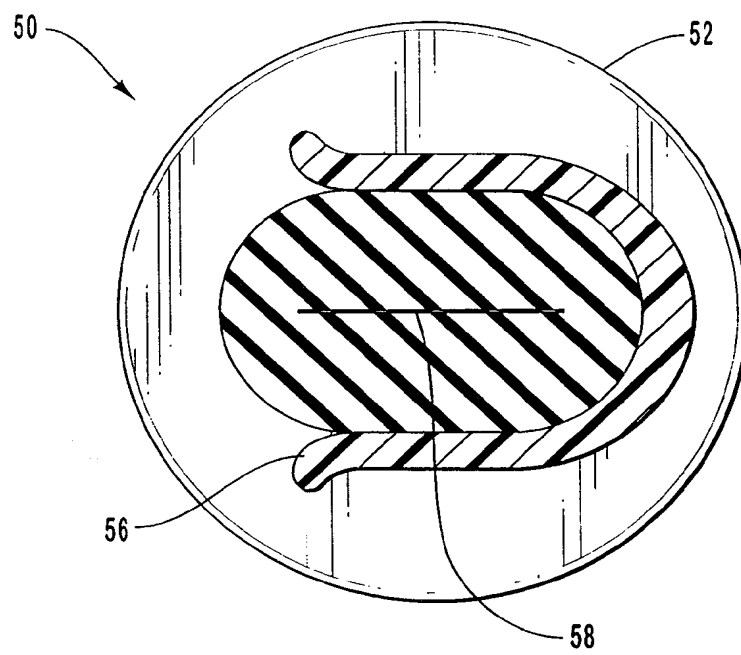


FIG. 3

3 / 4

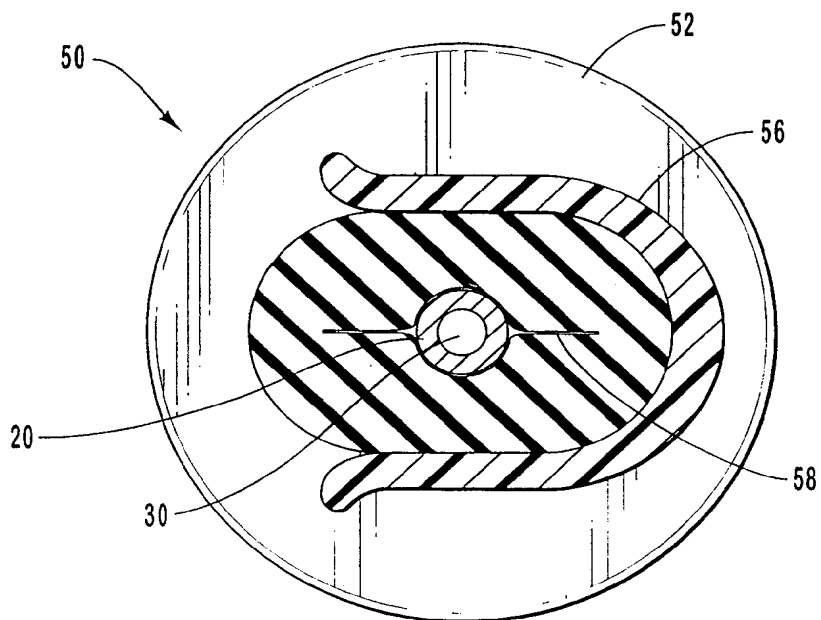


FIG. 4

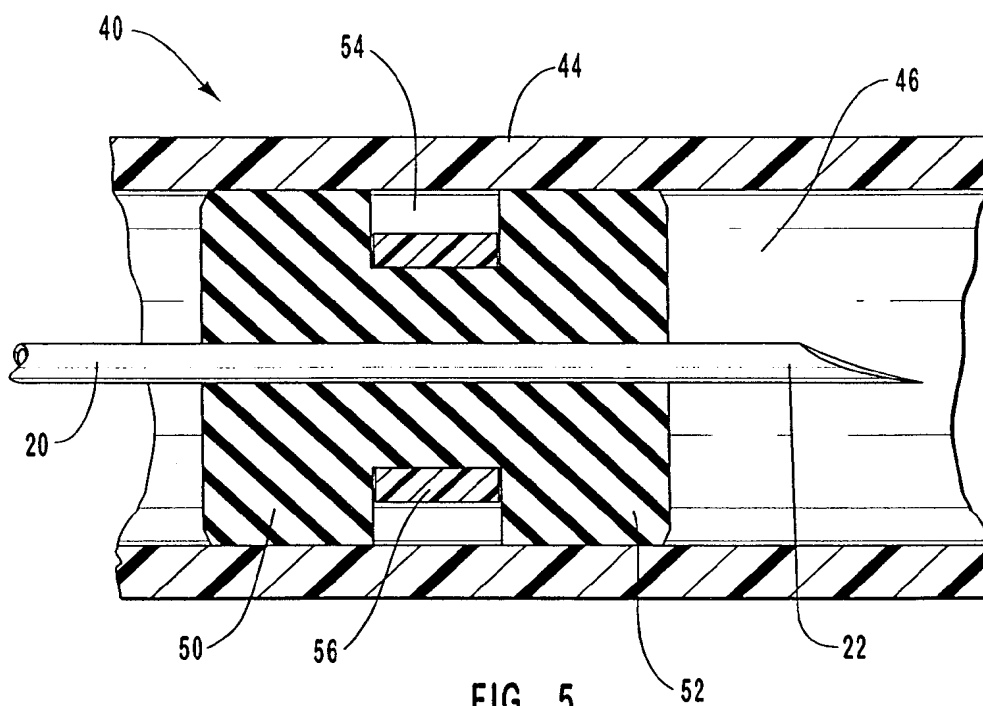


FIG. 5

INTERNATIONAL SEARCH REPORT

National Application No
PCT/US 99/19925

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M39/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 531 810 A (FULLEMAN) 2 July 1996 (1996-07-02) column 5, line 24 - line 38 column 6, line 56 -column 7, line 65 figures 1,2,4-6	1-10, 13-19
X	WO 98 23313 A (ELCAM PLASTICS) 4 June 1998 (1998-06-04) page 2, line 30 -page 4, line 11 page 6, line 19 -page 7, line 17 page 9, line 7 - line 29 figures 1-3,10-13	1,2,5,13
X	WO 96 23158 A (VERNAY LABORATORIES) 1 August 1996 (1996-08-01) page 19, line 29 -page 23, line 10 figures 3,14-16	13,18,19

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

22 December 1999

Date of mailing of the international search report

11/01/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Schönleben, J

INTERNATIONAL SEARCH REPORT

international application No.

PCT/US 99/ 19925

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20-23
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body
by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In International Application No

PCT/US 99/19925

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5531810 A	02-07-1996	AU 3550495 A	09-04-1996
		JP 10506189 T	16-06-1998
		WO 9609539 A	28-03-1996
WO 9823313 A	04-06-1998	US 5814024 A	29-09-1998
		US 5807348 A	15-09-1998
		EP 0964710 A	22-12-1998
WO 9623158 A	01-08-1996	US 5533708 A	09-07-1996
		AU 687667 B	26-02-1998
		AU 4700296 A	14-08-1996
		CA 2207754 A	01-08-1996
		EP 0805930 A	12-11-1997
		JP 10512946 T	08-12-1998